

EXHIBIT 2



The Honorable Ron Clark
United States District Court for the Eastern District of Texas
300 Willow Street, Suite 221
Beaumont, Texas 77701

June 17, 2015

Re: Civil Action No. 1:14-cv-00104; *Mark A. Barry, MD. v. Medtronic, Inc.*; In the
United States District Court for the Eastern District of Texas, Beaumont Division.

Judge Clark:

Medtronic has asked for leave to move for summary judgment on *pre-suit* damages on two bases: 1) failure to mark under 35 U.S.C. Section 287(a); and 2) for lack of knowledge of the patent or intent for indirect infringement of the patents.

Section 287(a) requires a patent owner to give notice of infringement of an apparatus claim to a defendant by direct communication that satisfies the requirements of the statute, or to “mark” the products that embody the patent with the patent number (or through virtual marking), before damages accrue. In the absence of such notice or marking, the statute states that filing of suit provides notice. Section 287(a) does not apply to method claims. *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1332 (Fed. Cir. 2010). Also, if only method claims are asserted from a patent that includes both method and apparatus claims, pre-suit damages can be awarded without any notice or marking. *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1316 (Fed. Cir. 2009).

The '358 patent-in-suit contains five method claims and no apparatus claims. Section 287(a) does not apply to the '358 patent's method claims. For this simple reason, Medtronic's argument that failure to mark prevents pre-suit damages in this case is wrong. As explained below, Medtronic's arguments on inducement are also flawed.

I. There are multiple fact issues concerning Medtronic's indirect infringement.

Medtronic incorrectly argues that there is no basis to believe that it knew of the patents-in-suit before the filing of this suit, and thus, it cannot have infringed the method claims prior to the filing of the suit, under 35 U.S.C. § 271(b).¹ However, unlike patent marking, there are no requirements of formal notice under § 271(b). As the Supreme Court held in *Global-Tech v. S.E.B.*, notice can be inferred from willful blindness: “a willfully blind defendant is one who

¹ Liability under § 271(b) requires knowledge of the patent and intent and action to induce infringement. *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F. 3d 1293, 1305 (Fed. Circ. 2006).

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takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts.” 131 S. Ct. 2060, 2070-71 (2011). Here, there is strong circumstantial evidence of at least “willful blindness” on Medtronic’s part, even before any discovery has been conducted on this issue.

A. There are fact issues as to inducement by Medtronic under 271(b)

i. Knowledge of the ‘358 Patent: Drs. Lenke and Bridwell Developed Medtronic’s CD Horizon Legacy

The evidence shows that Medtronic, contrary to its arguments, was aware of at least one of the patents-in-suit before this lawsuit was filed.

In a special advertising insert in a 2008 edition of Spine Journal, Medtronic published an article by Drs. Lawrence Lenke and Keith Bridwell called “Scoliosis and Chest Wall Derotation Utilizing Pedicle Screws and the Vertebral Column Manipulation (VCM) Instrument Set” Ex. H. The article is about Medtronic’s CD Horizon Legacy System, which is now accused of infringement in this case. Drs. Lenke and Bridwell are long-time colleagues and leaders of the Department of Orthopedic Surgery at Washington University in St. Louis, Missouri, and have very close ties to Medtronic, having received, through the 2000s, millions of dollars in grants from Medtronic.² See CV of Dr. Lenke, Ex. I.

² Funding Agency: Medtronic Sofamor Danek, Memphis, TN

Period: *March 2001 – February 2005*

Grant Title: Washington University Spine Research Center

Investigators: **Keith H. Bridwell, MD, Lawrence G. Lenke, MD, K. Daniel Riew, MD**

Funding: **\$1,494,604.00** (funded in full)

Funding Agency: Medtronic Sofamor Danek, Memphis, TN

Period: **October 2003 – September 2008/Renewed May 2009 – July 2009**

Grant Title: Prospective Pediatric Scoliosis Study (PPSS) (02-0689)

Investigators: **Lawrence G. Lenke, MD, Matthew B. Dobbs, MD, Keith Bridwell, MD, Scott J. Luhmann, Jr., MD*, Timothy R. Kuklo, MD*** (as of 2007)

Funding: **\$50,000.00** (funded in full)

Funding Agency: Medtronic Sofamor Danek, Memphis, TN

Period: **March 2005 – July 2009**

Grant Title: Washington University Spine Research Center

Investigators: **Keith H. Bridwell, MD, Lawrence G. Lenke, MD, K. Daniel Riew, MD, Timothy R. Kuklo, MD*** (as of 2007)

Funding: **\$1,948,615.00**

Funding Agency: Medtronic Sofamor Danek, Memphis, TN

Period: January 2000 – December 2001

Grant Title: *Genetic Manipulation of the Secondary Injury Cascade of Acute Spinal Cord Injury*

Investigators: Jueren Lou, PhD, F. Xu, PhD, **Lawrence G. Lenke, MD**

Funding: \$25,000.00 (funded in full)

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Further, Dr. Lenke's web page states that he designed, along with colleagues from Medtronic, Medtronic's "CD HORIZON® LEGACY™ Spinal System." Exh. J. This is consistent with the Spine Journal advertising article sponsored by Medtronic.

In addition, two patent applications were filed on February 9, 2006 that are related to Medtronic's CD Horizon Legacy System. The first listed Dr. Bridwell (among others) as an inventor, and the second listed Dr. Lenke (among others) as an inventor. A Dr. Kave is listed as an inventor on both applications. See U.S. Patent Appl. 11/350,914, Bridwell, Kave, et al., Ex. L; and U.S. Patent Appl. 11/350,915 Lenke, Kave, et al. Exh. K. It appears that Noreen Johnson, in-house patent counsel at Medtronic, supervised both applications. Letters from PTO to Noreen Johnson in 11/350,914 and 11/350,915, Ex. M & N.

Further, the prosecution of the two applications was closely related. For example, certain claims of the Bridwell '914 application were rejected for double patenting over certain claims of the Lenke '915 application. See USPTO Office Action 11/350,914, dated October 8, 2009, Ex. M.

In 2009, the Barry patent application that resulted in the '358 patent-in-suit was disclosed to the Patent Office by the inventors of the '914 Medtronic patent application. Ex. O, (dated December 8, 2009). Notably, this was after the Patent Office issued a Notice of Allowance for the Barry application on October 1, 2009. Ex. P. The application that resulted in the '358 patent-in-suit was never disclosed to the Patent Office during the prosecution of the '915 Medtronic patent application, despite the fact that the '914 and '915 patent applications were closely related, had common inventors, and were supervised by the same patent attorney. Moreover, Figure 1 of the '915 application portrays a device that appears similar to Figure 1 of the earlier-published Barry application, and there is strong evidence that Dr. Lenke was fully aware of Dr. Barry's work in 2004.³

In any event, Medtronic's citation in 2009 of the Barry application—after the Patent Office had issued a Notice of Allowance for the application—in one of Medtronic's applications related to the now-accused CD Horizon Legacy is strong evidence that Medtronic knew of at least one of the patents-in-suit before this litigation started. Indeed, a district court has recently held that knowledge of a patent application after notice of allowance was circumstantial evidence of knowledge of the patent. *Kid Stuff Marketing, Inc. v. Creative Consumer Concepts, Inc.*, 15-2620-JML, 2015 WL 3485759 (D. Kansas June 2, 2015) (holding on 12(b)(6) motion that

³ Dr. Lenke attended Dr. Barry's presentation at the July 2004 IMAST meeting and discussed it with him afterward. In addition, Medtronic was exhibiting at a conference (IPOS) in December 2004 during which Dr. Barry displayed a model of his completed apparatus. See Answer to Interrogatory 2. In 2006, Dr. Lenke applied for a patent on a system with the same functionality as Dr. Barry's system, and which appears similar in many ways (compare Figure 1 of '358 patent and Figure 1 of Dr. Lenke patent (U.S. Patent No. 7,655,008).

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knowledge of a patent application where prosecution had advanced to steps before issuance, and of other circumstantial evidence, was sufficient to make plausible that defendant had been willfully blind to the patent).

In this industry, where regulatory oversight by the FDA is pervasive, liability issues are present, and costs are inflated by those and other factors, patent protection is typically sought for innovations. Barry Declaration, Ex. A, ¶ 19. Even with no discovery yet on the issues above, the evidence shows that Dr. Lenke was aware of Dr. Barry's work by 2004, and that Medtronic was aware by December 2009 that the '358 patent had been allowed and would issue shortly. Thus, Medtronic's arguments suggesting that summary judgment is appropriate on this issue are misguided.

ii. Medtronic trained and promoted use of the methods in the '358 patent

A cursory review of Figure 1 of both Dr. Barry's patent and the later Lenke and Bridwell patents would alert a reader to similarities, as would examination of Dr. Bridwell's application to the cited Barry applications.

The above-referenced Spine Journal insert is, in effect, an advertisement for the CD Horizon Legacy VCM system—the accused system in this lawsuit—and concludes with the statement, “To inquire about Medtronic's medical education and training programs on vertebral column manipulation and derotation techniques, please call (800) 876-3133.” Ex. H.

Furthermore, Dr. Lenke has been a long time consultant for Medtronic, being paid over \$100,000 per year as a consultant for Medtronic in the relevant time period. Ex. Q. He also received millions in grants in the time period. He has received millions in royalties, consulting fees and training fees. For example, in the first three months of 2010, Dr. Lenke received nearly \$900,000 in royalties from Medtronic. Ex. S. In the first half of 2013, he received money for product development, training and royalties in excess of one million dollars. Ex. R. Furthermore, Medtronic owns the patent.

Medtronic's report for payments to physicians in 2010 and the Government's report for the first half of 2013, shows that Dr. Lenke received payments for training other surgeons. See Ex. R & S. Newspaper articles, as well as these disclosures of payments to physicians, show that in addition to grants, Dr. Lenke or companies controlled by him received significant financing from Medtronic. See Ex. Q, R, & S. Medtronic's training materials, promotion of its CD Horizon Legacy products, and training sessions induce infringement of the '358 (and other) Barry patents.

iii. Direct infringement by Medtronic

To the extent direct infringement under 271(a) by Medtronic is the subject of its motion, the contracts it had with Dr. Lenke for development and training of its product, and evolution to

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its newer versions of the CD Horizon Legacy and Solara, satisfy the requirements of *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111 (2014), because Medtronic provides parts of the apparatus in the '072 and '121 patents, and Dr. Lenke completes the apparatus and performs surgeries using the methods claimed in the '358 patent (typically with a Medtronic representative present). Dr. Lenke further can be said to be acting as an agent or on behalf of Medtronic when he trains other surgeons in the methods. Finally, most likely other doctors train surgeons in these methods and with this apparatus under Medtronic's control or pay. Section 271(a) does not require knowledge of the patent or intent to infringe. This joint infringement in light of a contractual relationship and payment for training and product development, is § 271(a) infringement.

II. Summary Judgment Without Discovery Is Inappropriate

Pursuant to Fed. R. Civ. P. 56(d), attached is the declaration of James Reed, requesting discovery on Medtronic's knowledge of the Barry applications and patents prior to any motion for summary judgment, plus information on other elements of direct and indirect infringement. While it is hoped that the discovery can be completed with a document request and 30(b)(6) deposition(s) of Medtronic (assuming it takes responsibility for collecting information from its agents, e.g., Dr. Lenke, Mr. Kave, Mr. Collier, Mr. Wolfe, Dr. Bridwell, and Ms. Johnson), it is possible follow up discovery maybe needed. Declaration of James Reed, Ex. T.

Respectfully submitted,

/s/ James Reed, Jr.
James L. Reed, Jr.